PARENT/GUARDIAN PERMISSION FORM

TITLE: Zinc Fortification Effects on Cognition, Psychoeducational Performance, Body Composition, Physical Fitness and Immune Function of Adolescents

INSTITUTION: USDA, ARS, Grand Forks Human Nutrition Research Center
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Who is doing this research study?

This research study is being conducted by the United States of Agriculture, Agricultural Research Service, Grand Forks Human Nutrition Research Center (**GFHNRC**). The principal investigators for this study are James G. Penland, PhD, a research psychologist, and Henry C. Lukaski, PhD, a research physiologist. Dr. Penland has been studying the relationship between nutrition and behavior for more than 15 years and has participated in three previous studies involving school-aged children. Dr. Lukaski has been studying the relationship between nutrition and body composition and physical fitness for more than 20 years. The project coordinator is Dr. Jacque Gray, a research psychologist at the GFHNRC, who has extensive experience working with adolescent children.

Why are we doing this study?

Zinc is a common mineral nutrient contained in our diets, the foods we eat and the fluids we drink. We know that eating too little zinc can impair brain function and behavior in developing animals. About 40 years ago, researchers found that zinc was necessary for growth in adolescent children. Since that time however, human studies of zinc nutrition and behavior have only been conducted with infants, young children and adults. Two studies of children aged 6-9 years found that adding 20 milligrams of zinc to the diet each day improved cognition (for example, attention, memory and reasoning), motor skills and social adjustment. Two other studies found that adding 30 or 50 milligrams of zinc to the diet each day improved memory of adults. Other studies have shown a relationship between zinc nutrition and body composition, physical fitness and immune function, but none of these have been conducted with adolescents. The National Academy of Sciences recently concluded that there is a great need to determine the importance of zinc for adolescent development and function because current dietary recommendations for this age group are based solely on knowledge about adults and young children.

This research study will determine in adolescents your child's age whether zinc is beneficial to cognition, social adjustment, school performance, body composition, physical fitness and immune function.

Is my child eligible for this study?

All children, boys and girls, enrolled in the 7th grade and attending Grand Forks Public Schools during the 2002-2003 school year are eligible to participate in this study, with the following exceptions. Participation requires both the permission of a parent/guardian and the assent of the student; in other words, both the student and a parent/guardian must agree and want to take part in the study. Students who currently consume vitamin or mineral supplements must agree to stop taking those supplements for the duration of the study. Students who have a known allergy or intolerance to the orange and apple juice being served in this study (described below) will not be allowed to participate. Students with physical or psychological problems (e.g., asthma, diabetes, learning disorder, attention deficit hyperactivity disorder) will be allowed to take part, but may be excused from participating in some assessments at the written request of his or her parent/guardian or physician.

What will I have to do, when, and how long will it take?

A parent/guardian of each participating student will be asked to fill out several questionnaires or forms. These forms can be completed at home and will require a total time of about 1-2 hours during the 15-week study. You can get help completing these forms from the project coordinator.

Demographics Questionnaire

Provides basic background information about: 1) your child, such as sex, age, racial and ethnic group; 2) you, such as age, education and occupation of parents/guardians; and, 3) your household, such as number and ages of other children in the family, and household income.
(At the beginning of the study; about 10 minutes)

Health History

Provides information about your child's current and past medical and psychological health.
(At the beginning of the study; about 20 minutes)

Child Behavior Checklist

Provides information about your child's mental, physical and social abilities and skills, school performance, and any behavioral problems.
(Once at the beginning and once at the end of the study; about 30 minutes each time)

Health Log

Provides information about any illnesses, infections, injuries, etc. experienced by your child during the study, and how bad and how long each problem lasted. You will be given the log to record this information and all necessary instructions at the beginning of the study.
(Only as needed; about 2 minutes each entry)

What will my child have to do, when, and how long will it take?

Each participating student will be given one of 3 possible dietary treatments (described below) for 12 weeks. Several measurements (described below) of psychological function, and physical health and fitness will be made during a 3-week period before the treatment and again during the last three 3 weeks of treatment. The study will be conducted between August and December 2002, and last about 15 weeks. All measurements will be made at the student's school, either in the school building or on the GFHNRC's Mobile Nutrition Research Laboratory. Some measurements will be done before school and some will be done during school hours; therefore your child may miss part of several classes during the 15-week study. Because they believe the experience will be educational, teachers will give your child permission to miss class time to take part in this study.

Dietary Treatment

The dietary treatment will be common orange or apple juice that contains: (A) no extra zinc, (B) 10 milligrams of extra zinc, or (C) 20 milligrams of extra zinc. The current Recommended Dietary Allowance for zinc for adolescents your child's age is10 milligrams a day. Your child will be randomly assigned to always get juice containing the same amount of zinc (A, B or C), but your child will never know which of the three he or she is being given. Each of the three treatments will be given to at least 50 boys and 50 girls.

Your child will be given the orange or apple juice to drink each regular school day for 12 weeks during the fall term of the 2002 school year. A 4-ounce cup of juice will be distributed in your child's school lunchroom by GFHNRC staff. Your child's name will be used to identify your child and make sure he or she gets the correct juice each day. YOUR CHILD MUST DRINK THE ENTIRE CUP OF JUICE EACH DAY AS SOON AS IT IS GIVEN TO HIM OR HER.

Dietary Intake

What your child usually eats and drinks will be measured in two ways. First, your child will fill out a questionnaire asking him or her how often (for example, daily, weekly or monthly) he or she eats certain foods or drinks certain fluids (for example, water, soda pop or milk). Registered dietitians from the GFHNRC will provide instructions for completing the questionnaire. Your child will complete the questionnaire once at the beginning and once at the end of the study, and it will take about 30 minutes each time. Second, your child will meet with a trained interviewer supervised by a registered dietitian who will ask your child to recall (remember) what he or she ate and drank the previous day. Your child will meet with the interviewer two times during the study, and the meeting will take about 15 minutes each time.

Blood Draw

Blood will be drawn from your child's arm to measure zinc and other minerals and vitamins, and to measure general health and immune function. Blood will be drawn by an experienced, specially trained GFHNRC technician supervised by a physician, with sterile needles and syringes similar to those used in your doctor's office or a clinic. Approximately 35 milliliters (2.3 tablespoons) of blood will be drawn twice, once at the beginning and once at the end of the study, for a total of 70 milliliters (4.7 tablespoons) during the 15-week study. This compares with 90 milliliters (6 tablespoons) drawn at one time from healthy adolescents your child's age in the Third National Health and Nutrition Examination Survey, 1988-1994, conducted by the Centers for Disease Control. YOUR CHILD MUST NOT EAT ANY FOOD OR DRINK ANYTHING OTHER THAN WATER AFTER 10 PM THE NIGHT BEFORE A BLOOD DRAW, which will occur no later than 9:30 am the next morning. Your child will be given orange or apple juice and a snack after the blood draw, and will be watched for at least 10 minutes to make sure he or she is okay.

Cognitive and Psychomotor Function

Cognitive processes (for example, attention, memory, reasoning) and sensory-motor and spatial skills (for example, eye-hand coordination) will be measured by having your child perform simple tasks on a personal computer. Examples of tasks include tapping a key on the keyboard as fast as possible, using a computer mouse to track an object moving across the computer screen, searching a group of common objects for two of a kind, memorizing and recognizing lists of words or simple geometric patterns, and categorizing objects. Tasks will be performed under the guidance of an experienced, specially trained GFHNRC technician. These measurements will occur once at the beginning and once at the end of the study, and take about 60 minutes each time.

Youth Self Report

Your child will complete the Youth Self Report, a companion questionnaire to the Child Behavior Checklist completed by the parent/guardian. This questionnaire provides information about your child's mental, physical and social abilities and skills, school performance, and any behavioral problems. An experienced, specially trained GFHNRC technician will provide instructions for completing the questionnaire. Your child will complete the questionnaire once at the beginning and once at the end of the study, and it will take about 30 minutes each time.

Vision and Auditory Function

To ensure that your child does not have vision or hearing problems that might affect other measures we are making, his or her vision and hearing will be tested by an experienced, specially trained GFHNRC technician using standard screening equipment and procedures. These tests take about 20 minutes total and will be done only once during the first 3 weeks of the study. Note that your child may still take part in this study even if he or she wear glasses, contact lenses or a hearing aid.

Anthopometry (Growth and Body Composition)

Several measurements will be made to determine possible treatment effects on growth and body composition; that is, the amount and distribution of bone, muscle, fat and fluids. Height and body weight will be determined by using a stadiometer and scale just like those used in your doctor's office. Circumferences (distance around) of your child's

upper arm, waist, hip, thigh and calf will be determined with a tape measure and set of calipers. Skinfold thickness, a measure of body fat, will be determined by gently pinching the skin, holding the pinched area, then measuring the thickness of the pinched skin and fat tissue at the front and back of your child's upper arm, back, waist, thigh and calf with a set of calipers. Your child will wear his or her usual physical education uniform (shorts and short -sleeved shirt) but no shoes. Measurements at the waist, hip and thigh will be done through the clothing to minimize possible embarrassment. All growth and body composition measurements will be done behind a portable screen in the school gymnasium to ensure your child's privacy; a female adult will always be present during measurements of girls. An experienced, specially trained GFHNRC technician will make all growth and body composition measurements. These measurements will be made once at the beginning and once at the end of the study, and take about 20 minutes each time.

Bioelectrical Impedance (Body Composition)

Another type of measurement, known as bioelectrical impedance, will also be used to determine possible treatment effects on body composition and to provide further information about the usefulness of this technique with adolescents. Your child will lie on a table and electrodes will be taped on his or her shoulder, elbow, wrist, hip, knee, and ankle. A safe, painless, unnoticeable low energy electrical current of 100 microamps at radio frequencies ranging from 1 kilohertz to 1 megahertz will be applied. This radio-frequency current is the same amount of electrical current that your child is exposed to when he or she is watching television or listing to the radio. Your child will not feel this current. The amount of bone, muscle, fat and fluids will be determined based on how your child's body conducts this electrical current. Your child will wear his or her usual physical education uniform (shorts and short -sleeved shirt) but no shoes or socks. An experienced, specially trained GFHNRC technician will make all bioelectrical impedance measurements. These measurements will be made once at the beginning and once at the end of the study, and take about 10 minutes each time.

Physical Fitness

A nationally standardized physical fitness test (FitnessGram, Human Kinetics Publishers Inc, Champaign IL) will be administered to your child to measure aerobic capacity, muscle strength and endurance, and flexibility. This test compares your child's activity patterns and fitness to national norms for school-aged children. Specially trained technicians supervised by GFHNRC staff will make all activity and fitness measurements. These measurements will be made once at the beginning and once at the end of the study, and take about 2 hours (2 gym classes) each time.

How will the teachers and schools be involved in this study?

Teachers will complete the Teacher's Report Form, a companion questionnaire to the Child Behavior Checklist completed by the parent/guardian and the Youth Self Report completed by the student. This questionnaire provides information about your child's mental, physical and social abilities and skills, school performance, and any behavioral problems.

Teachers and school administrators, with assistance from the principal investigators and Team Nutrition, will develop several classroom activities with subject matter that complements what students will be learning from their participation in this study.

The Grand Forks Public School District will permit the GFHNRC to locate its Mobile Nutrition Research Laboratory on school property, and some study activities and measurements will be done in school buildings. Disruption to ongoing school activities will be minimal.

Study findings and interpretation (without identification of individual students) will be provided to school administrators, teachers and appropriate health officials (for example, dietitians in the Child Nutrition Program). The nutrient content of school-provided breakfasts and lunches will be determined by calculation and chemical analysis at the GFHNRC, and results provided to school administrators and appropriate health officials.

Who will get the results of this study?

At the conclusion of the study, individual students' results with appropriate interpretation will be made available

to their parents/guardians, while study results and interpretation (without identification of individual students) will be provided to school administrators, teachers and appropriate health officials (e.g., Child Nutrition Program). A summary of study findings will also be sent to parents/guardians. The principal investigators will meet individually and with groups of participants as requested to review and interpret individual and group findings. Results of individual students will not be made available to anyone other than their parents/guardians without their explicit written release of information, clearly specifying the limits of information to be released. You will be strongly encouraged to share and discuss individual results and the study's findings with your child.

What are the benefits of taking part in this study?

Neither you nor your child will be paid any money for taking part in this study. However, your child, his or her school, and society will benefit in several ways if your child and you take part in this study.

Your child will directly benefit by learning more about nutrition (what we eat and drink) and the importance of nutrition for your child's health and fitness, how your child does in school, your child's ability to think, and how your child feels and socializes with others. Your child will learn more about many different areas of science, including psychology (the study of behavior), physiology (the study of function), biology (the study of living things), chemistry (the study of substances) and medicine (the study of health and disease); your child will even learn some new things related to geography, computers, electricity and mathematics. Your child will learn about the basics of research and conducting an experiment. We believe your child's experience with the measurements made during the study, and related classroom activities, will increase his or her interest in general science and advanced education. And very importantly, by taking part in this study your child (and you) will gain satisfaction and pride from knowing that he or she has participated in a worthwhile research study that will benefit society because it will increase knowledge of nutrition and its benefits for all people.

Your child's school and school district will directly benefit from your child taking part in this study because they will learn more about their students (as a group, not your individual child) so they can improve their educational programs and benefit future students. Schools will also learn more about their school breakfast and lunch programs.

Your community and society as a whole will benefit from your child taking part in this study because the results will provide needed information about the possible benefits of zinc for children your child's age. The Food and Nutrition Board of the National Academy of Sciences recently found that there is a great need to determine the nutritional benefits of zinc for adolescents your child's age because current dietary recommendations for this age group are based solely on knowledge about adults and younger children. Therefore, scientists, policy makers, nutritionists and other health professionals, the food industry, and even you and your child eventually may use the results from this study.

What are the risks of taking part in this study?

Confidentiality

The greatest risk involved in taking part in this study is the possibility of losing privacy of personal information. The following steps will be taken to minimize this risk. All information and measurements will be identified by the student's unique school identification number rather than by name. Only GFHNRC staff will collect and enter information and measurements into a password-coded computer system using only the student's identification number. Individual information and measurements will not be made available to anyone other than the parents/guardians without their explicit written release of information that also clearly specifies the limits of information to be released. Confidentiality will be stressed with all individuals involved, including school administrators and teachers, parent volunteers, and GFHNRC staff. All permissions, assents, personal information, laboratory, nutritional, psychological and physiological data will be kept in a locked file at the GFHNRC for at least three years after completion of the study. Access will be limited to approved GFHNRC staff members, inspectors and federal agencies as provided by federal regulation. When eventually destroyed, any paper that contains student or parent/guardian names or personal information will be shredded and any computer disks will be erased. Results from this study may be published in a scientific journal, but only in a form not identifiable with any individual student. Because family members are also

protected as secondary subjects, information obtained about these individuals from the demographics and health history questionnaires also will be kept strictly confidential.

Demographics Questionnaire

There are no known risks associated with this procedure. However, some parents/guardians may feel uncomfortable answering some of the personal items on this questionnaire. If there are any concerns about completing this questionnaire, the parent/guardian may discuss these with the field coordinator or principal investigators.

Health History

There are no known risks associated with this procedure. However, some parents/guardians may feel uncomfortable answering some of the personal items on this questionnaire. If there are any concerns about completing this questionnaire, the parent/guardian may discuss these with the field coordinator or principal investigators.

Health Log

There are no known risks associated with this procedure. However, some parents/guardians may feel uncomfortable reporting some of the personal items in this log. If there are any concerns about completing this log, the parent/guardian may discuss these with the field coordinator or principal investigators.

Child Behavior Checklist

There are no known risks associated with this procedure. However, some parents/guardians may feel uncomfortable answering some of the personal items on this questionnaire. If there are any concerns about completing this questionnaire, the parent/guardian may discuss these with the field coordinator or principal investigator (Dr. Penland). This measure will be made in accordance with all standards established for test administration, interpretation and confidentiality by the American Psychological Association.

Dietary Treatment

The orange or apple juice used as the dietary treatment in this study is commercially available juice that contains specific amounts of zinc. Because adolescent children commonly drink such juice without any adverse effects and because the amounts of zinc fortification in this study have been used in several previous studies of younger children and adults without any adverse effects, there are no known risks of drinking the juice in this study. However, some students may show an allergic reaction to the orange or apple juice. Also, some students may get tired of drinking the same juice 5 days each week for 12 weeks.

Dietary Intake

There are no known risks or discomforts associated with these procedures.

Blood Draw

During any blood draw, there may be some discomfort as the needle enters the skin, but this lasts only a few seconds. A small bruise may develop in about 1 out of every 10 people, but this goes away in two weeks or less. In about 1 out of every 1000 people, an infection may develop where the needle enters the skin, but this is usually treated with common antibiotics. If an infection develops, the GFHNRC will pay for necessary medical care. A very few people may feel lightheaded (dizzy) or nauseous for a very brief time. To reduce this feeling, every student will be given orange or apple juice and a snack immediately following the blood draw, and watched for at least 10 minutes to make sure he or she is okay.

Approximately 35 milliliters (2-1/3 tablespoons) of blood will be drawn twice, for a total of 70 milliliters (4-2/3 tablespoons) during the 15-week study. This compares with 90 milliliters (6 tablespoons) drawn at one time from healthy adolescents your child's age in the Third National Health and Nutrition Examination Survey, 1988-1994, conducted by the Centers for Disease Control. Your child's iron status will be determined after the first blood draw and if his or her hemoglobin is less than 11 grams per deciliter then you will be notified and your child will be referred

to his or her local doctor for evaluation. The student's doctor would then determine whether blood could be drawn again at the end of the study.

The GFHNRC staff is very aware of the risk of a blood spill or surface contamination. They are trained in and use Universal Blood and Body Fluid Precautions. Personal protective equipment such as gloves, needles with sheaths, appropriate disposal containers, and decontamination supplies will be used.

Cognitive and Psychomotor Function

There are no known risks associated with performing simple tasks on the computer. However, some students may have concerns regarding their performance. If there are any concerns about these measurements, the student or his or her parents/guardians may discuss these with the field coordinator or principle investigator (Dr. Penland).

Youth Self Report

There are no known risks associated with filling out this questionnaire. However, some students may feel uncomfortable answering some of the personal questions. If there are any concerns about this measurement, the student or his or her parents/guardians may discuss these with the field coordinator or principle investigator (Dr. Penland). This measure will be made in accordance with all standards established for test administration, interpretation and confidentiality by the American Psychological Association.

Vision and Auditory Function

There are no known risks or discomforts associated with the vision or hearing tests. You will be notified if your child's vision or hearing fall outside normal limits with correction.

Anthropometry (Growth and Body Composition)

There are no known risks associated with any of the measurements of growth or body composition. However, some students may feel a little discomfort for a short time when their skin is gently pinched to measure skinfold thickness, and some students may feel a little discomfort for a short time when the adhesive (sticky) tape containing the electrodes are removed after measuring bioelectrical impedance. Measurements at the waist, hip and thigh will be done through the clothing to minimize possible student embarrassment. All growth and body composition measurements will be done behind a portable screen to ensure student privacy and a female adult will always be present during assessment of girls.

Physical Fitness

The physical fitness battery measures student performance on activities typical of those routinely done in school physical education classes; therefore, no additional risks or discomforts are associated with this measurement. However, some students may have concerns about their performance. If there are any concerns about this measurement, the student or his or her parents/guardians may discuss these with the field coordinator or principle investigator (Dr. Lukaski).

Stopping Vitamin and Mineral Supplements

Although the orange or apple juice used in this study naturally and through commercial fortification contain vitamins and minerals other than zinc, it will not provide all vitamins or minerals (or like amounts) that a child might be taking prior to participating in this study. Therefore, stopping all vitamin and mineral supplementation as a requirement of taking part in this study may pose a slight risk for a child with a very poor diet who usually takes such supplements. If your child regularly takes a vitamin or mineral supplement and has a very poor diet and you are concerned about this risk, you are advised to talk with your physician or dietitian before you permit your child to participate.

What if my child and I agree to take part in this study, but then decide we don't want to continue?

Participation in this research study is entirely voluntary. Your child and you will be free to withdraw from (drop

out of) the study at any time. Further, withdrawing from the study will not affect your child's status at school, nor will it keep your child or you from taking part in future GFHNRC studies. Please contact the study coordinator or the principal investigators if you or your child decide you no longer wish to participate.

Can my child be dismissed from the study?

We reserve the right to dismiss (drop) your child from the study if he or she does not drink the orange or apple juice each day or does not participate in the measurements described above as scheduled. Minor exceptions may be allowed if they do not interfere with the main objective of the research. For example, if your child cannot drink the juice or must reschedule measurements due to a brief illness or absence, he or she likely will not be dismissed. Each situation will be handled individually, and the student and his or her parents/guardians will be involved in the final decision. Dismissal will not affect the status of your child at school. Students with physical or psychological problems (e.g., asthma, diabetes, learning disorder, attention deficit hyperactivity disorder) may be excused from participating in some assessments at the written request of his or her parent/guardian or physician.

What if my child gets sick or develops a health problem unrelated to this study?

Common illnesses, muscle strains, physical injuries and previously unrecognized health problems may occur at some time during this study, but be unrelated to taking part in the study. Each situation will be handled individually, and discussed with the parents/guardians and, if appropriate, the student. If the problem interferes with the research, then the student will be dismissed from the study. If the problem does not interfere with the research, then whether or not the student continues in the study will be the choice of the parents/guardians and student.

What if my child gets sick or is injured because he or she took part in this study?

As described above, there are few known risks associated with taking part in this study. However, the GFHNRC will pay all costs for treatment of any condition caused by taking part in the research study. If a student is injured while taking part in this research study as a result of the negligence of a United States Government employee who is involved in this research project, the student may be able to be compensated for his or her injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to the student and his or her parents/guardians.

Who can answer my questions?

You and your child can ask questions about any aspect of this study at any time by asking any member of the GFHNRC staff or by calling the project coordinator, Dr. Jacque Gray, at 701-795-8343, or the principal investigators, Dr. James Penland at 701-795-8471 or Dr. Hank Lukaski at 701-795-8429. You can also let any of the teachers or other school staff know that you have a question and they will have a GFHNRC staff member contact you to answer your question. Any questions about your or your child's rights as a research subject can be answered by the Institutional Review Board at the University of North Dakota (701-777-4279).

I understand, want to participate, and give permission for my child to take part in this study.

My signature below means that I have read this form and had all my questions answered, and that I understand what will happen in the study, what is expected of me and my child, and the benefits and risks of participating. My signature on this form also means that I want to participate and give my permission for my child to take part in this study. I understand that I will receive a copy of this permission form.

_____	_____
PRINT Student Name	PRINT Parent/Guardian Name
_____	_____
Parent/Guardian Signature	Date

Note. Only one parent/guardian is required to give permission.